

REMARKS

The Office Action dated December 31, 2004, has been received and reviewed.

Claims 1-21 are currently pending and under consideration in the above-referenced application. Each of claims 1-21 stands rejected.

Reconsideration of the above-referenced application is respectfully requested.

Claim Amendment

It is proposed that claim 8 be amended to correct an antecedent basis issue therein, as a “waveguide surface” does not appear in any of the claims from which claim 8 depends. It is also proposed that the dependency of claim 8 be changed so that claim 8 now depends from claim 4 rather than from claim 7.

This proposed amendment does not narrow the scope of claim 8 or of any of the other claims that remain pending in the above-referenced application.

Rejections Under 35 U.S.C. § 102(e)

Each of claims 1-21 stands rejected under 35 U.S.C. § 102(e) for reciting subject matter which is allegedly anticipated by the subject matter described in U.S. Patent 5,747,274 to Jackowski (hereinafter “Jackowski”).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Notably, patent applicants are their own lexicographers and, thus, determine the meanings of the various terms that appear in the claims of their patent applications. M.P.E.P. § 2173.01. In this regard, the meaning of every term in a claim should be determined from the descriptive portion of the specification. M.P.E.P. § 608.01(o). “When the specification states the meaning

that a term is intended to have, the claim is examined using that meaning . . ." M.P.E.P.

§ 2173.05(a), citing *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

Jackowski describes that multiple assays for different analytes may be conducted on a single sample that is obtained at a single point in time. Col. 22, lines 12-14. Thus, the amounts of markers that are *simultaneously present* in the sample may be accurately determined. Col. 22, lines 15-19. Assays for each of the analytes of interest may then be performed within a given time frame after the sample is obtained. Col. 22, lines 7-8.

As used in Jackowski, the term "simultaneous" does not have its ordinary meaning or that used in the specification of the above-referenced application. Rather, as indicated at col. 22, lines 2-19, the term "simultaneous" is not used in Jackowski to indicate that analysis of different analytes occurs concurrently, but that the analysis occurs within a given period of time (*e.g.*, thirty minutes) and that each analysis is performed on part of the same sample.

The description of Jackowski is also limited to determinations that occur at single points in time, although a collection of single points in time, which correspond to different assays conducted on parts of a single sample, may occur within a give period of time. Col. 22, lines 2-19; *see also* col. 22, lines 2-12; col. 29, lines 50-63, col. 30, lines 18-26; col. 35, lines 60-68.

Independent claim 1 of the above-referenced application is directed to a method for performing an assay. The method of independent claim 1 includes, among other things, substantially simultaneously evaluating the presence of a plurality of analytes in a sample. At least one of the plurality of analytes has known parameters that are indicative of an acute metabolic or disease state. In addition, the method of independent claim 1 includes substantially simultaneously determining concentrations of each of the plurality of analytes in the sample. The substantially simultaneous determination is continued until at least one of the analytes has been reliably determined to be present in an amount that is indicative of a metabolic or disease state. Once the amount of at least one of the analytes has been reliably determined, that determination is reported.

In contrasting the subject matter recited in independent claim 1 to that described in Jackowski, it is apparent that Jackowski does not anticipate several elements of independent claim 1, as would be required to maintain the 35 U.S.C. § 102(e) rejection of independent claim 1.

First, it is respectfully submitted that Jackowski does not expressly or inherently describe that multiple analytes of a sample may be substantially simultaneously evaluated. The meaning of the term “simultaneously,” as used in independent claim 1, should be determined from the specification of the above-referenced application rather than from the meaning that Jackowski has supplied for that term. *See M.P.E.P. §§ 608.01(o); 2173.01; and 2173.05(a).* The specification of the above-referenced application, at paragraphs [0072], [0078], and, in particular, [0121], makes it extremely clear that two or more analytes in a sample are evaluated at substantially simultaneously, or at substantially the same time or substantially concurrently. Jackowski, in contrast, clearly indicates that different analytes in a sample need not be evaluated concurrently. Col. 22, lines 6-12. Therefore, Jackowski does not anticipate the element of “substantially simultaneously evaluating the presence of a plurality of analytes in a sample” recited in independent claim 1.

Second, for the same reasons Jackowski does not expressly or inherently describe, or anticipate, “substantially simultaneously evaluating . . . ,” it is respectfully submitted that Jackowski does not expressly or inherently describe, or anticipate, “substantially simultaneously determining concentrations of each of the plurality of analytes in the sample,” as is required by independent claim 1.

Third, it is respectfully submitted that Jackowski neither expressly nor inherently describes “*continuing* a substantially simultaneous determination” of the presence of at least one analyte in a sample “*until* the at least one analyte has been reliably determined to be present in an amount indicative of a metabolic or disease state . . . ” (emphasis supplied). The term “*continuing*” clearly indicates that the determination of that at least one analyte is effected over a period of time, rather than at a single point in time. The description of Jackowski is, however, limited to determining the amount of each analyte in a sample at a single point in time.

Therefore, Jackowski does not anticipate “continuing [a] substantially simultaneous determination until . . . at least one analyte has been reliably determined to be present in an amount indicative of [a] metabolic or disease state . . .”

In view of the foregoing, it is respectfully submitted that, under 35 U.S.C. § 102(e), independent claim 1 recites subject matter which is allowable over that described in Jackowski.

Each of claims 2-21 is allowable, among other reasons, for depending either directly or indirectly from claim 1, which is allowable.

Claim 2 is additionally allowable because Jackowski includes no express or inherent description that “evaluating the presence of at least one other analyte in [a] sample” may *continue* after a report of a reliable determination that at least one analyte in the sample is present in an amount which is indicative of a metabolic or disease state. Again, the description of Jackowski is limited to effecting evaluations of the presence of analytes in a sample at single points in time rather than continuously.

Claim 7 is further allowable since Jackowski neither expressly nor inherently describes “correlating a rate of reaction between . . . at least one analyte and [a] corresponding reactive element to a concentration of the at least one analyte.”

Claim 8 is also allowable because Jackowski does not expressly or inherently describe that a substantially simultaneous determination of the presence of at least one analyte in a sample may be effected by reacting at least one analyte in a sample with a corresponding reactive element, the corresponding reactive element being one of a plurality of reactive elements that are arranged in one or more patterns on the surface of a waveguide.

Claim 10 is additionally allowable since Jackowski lacks any express or inherent description of stimulating a light signal from a reactive element, which is indicative of a rate of reaction between the analyte of interest and the type of reactive element from which the light signal is stimulated.

Claim 12 depends from claim 10 and is further allowable because there is no express or inherent description in Jackowski of correlating a rate of reaction between at least one analyte and a corresponding reactive element to a concentration of the at least one analyte.

For these reasons, withdrawal of the 35 U.S.C. § 102(e) rejections of claims 1-21 is respectfully requested.

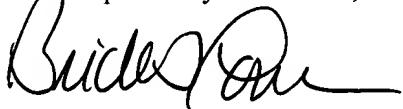
Entry of Amendments

It is respectfully requested that the proposed claim amendments be entered. The proposed amendments do not introduce new matter into the application, nor would they require an additional search. Moreover, by correcting an antecedent basis problem in claim 8, the number of issues that remain for purposes of appeal is reduced. In the event that a decision is made not to enter the proposed claim amendments, entry thereof upon the filing of a Notice of Appeal in the above-referenced application is respectfully requested.

CONCLUSION

It is respectfully submitted that each of claims 1-21 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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